k123775

510(k) Summary
Liquichek Spinal Fluid Control

JAN 3 1 2013

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

Suzanne Parsons
Regulatory Affairs Manager
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Date of Summary Preparation

January 28, 2013

2.0 Device Identification

Product Trade Name:	Liquichek Spinal Fluid Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Review Panel:	Clinical Chemistry and Clinical Toxicology Devices
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Spinal Fluid Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K990888

4.0 Description of Device

Liquichek Spinal Fluid Control is a human based control with added constituents of human and animal origin, chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

Table 1: Product Catalog Description

Level	Catalog Number	Configuration
Level 1	303	6 x 2.5 mL
Level 2	304	6 x 2.5 mL
Bilevel MiniPak	302X	2 x 2.5 (1 per level) mL

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Spinal Fluid Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

The new Liquichek Spinal Fluid Control claims substantial equivalence to the Liquichek Spinal Fluid Control currently in commercial distribution (K990888). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Similarities and Differences between the new and predicate device

Characteristics	Liquichek Spinal Fluid Control (New Device)	Liquichek Spinal Fluid Control (Predicate Device, K990888)
	Similarities	
Intended Use	Liquichek Spinal Fluid Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Liquichek Spinal Fluid Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Diluted Human serum	Diluted Human serum
Storage Unopened (Shelf life)	At 2 - 8 °C until the expiration date	At 2 - 8 °C until the expiration date
	Differences	
Fill Volume	2.5 mL	3 mL
Open Vial Stability	30 days at 2 - 8 °C on board Siemens Dimension Vista instrument	30 days at 2 - 8 °C
Analytes	**Contains:** Albumin Chloride Glucose Immunoglobulin G (IgG) Lactate(Lactic Acid) Lactate Dehydrogenase (LDH) Protein Total Sodium **Does not contain:** Immunoglobulin M (IgM) Globulin (α_1, α_2, β, γ) Immunoglobulin A (IgA) Prealbumin	**Contains:** Albumin Chloride Glucose Immunoglobulin G (IgG) Lactate(Lactic Acid) Lactate Dehydrogenase (LDH) Protein Total Sodium Immunoglobulin M (IgM) Globulin (α_1, α_2, β, γ) Immunoglobulin A (IgA) Prealbumin

8.0 Statement of Supporting Data

Stability studies have been performed and acceptance criteria were met for Liquichek Spinal Fluid Control to determine the stability claims. Product claims are as follows:

Open Vial:	30 days at 2 to 8°C
Shelf Life Stability:	2 Years at 2 to 8°C

9.0 Conclusion

Based on the performance characteristics indicated above, Bio-Rad's Liquichek Spinal Fluid Control is substantially equivalent to the predicate device K990888.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 31, 2013

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k123775
Trade/Device Name: Liquichek Spinal Fluid Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: December 6, 2012
Received: December 10, 2012

Dear Ms. Suzanne Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k123775

Device Name: **Liquichek Spinal Fluid Control**

Indications for Use:

Liquichek Spinal Fluid Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

The following analytes are listed in the package insert:

- Albumin
- Chloride
- Glucose
- Immunoglobulin G (IgG)
- Lactate (Lactic Acid)
- Lactate Dehydrogenase (LDH)
- Protein Total
- Sodium

Prescription Use ___X___ And/Or Over the Counter Use ____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health (OIR)

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